

## **REMARKS**

### **I. Status of the Application**

Claims 1-37 are presently pending in the application. Claims 1, 6, 13, 14 and 25-28 have been amended. Claims 38-49 have been cancelled without prejudice to the filing of any appropriate continuation applications as being directed to non-elected subject matter. Applicant gratefully acknowledges that claims 13, 14 and 25-28 have been indicated allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 1-12, 15-24 and 29-37 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Dunn et al., 4,655,777.

Applicant has amended the claims to more clearly define and distinctly characterize Applicant's novel invention. Support for the amendments can be found throughout the specification and claims as originally filed. Specifically, support for the amendments to claims 1 and 6 to recite "sintered together to form the scaffold" can be found at least at page 5, lines 11-12 of the specification, where Applicant teaches "bioactive fibers are sintered together to form a scaffold".

Claims 13, 14 and 25-28 were amended into independent form. Claim 13 was amended to recite the limitation "a sintered scaffold material comprising glass or ceramic fibers" from claim 1. Applicant did not amend claim 13 to include the limitation from claim 1 pertaining to porosity, as Applicant believes that claim 13 as amended is novel and nonobvious over the cited art. Claim 13 was further amended to correct formal matters. Claim 14 was amended to recite the limitation "a sintered glass scaffold comprising glass fibers" from claim 6. Applicant did not amend claim 14 to include the limitation from claim 6 pertaining to a coating of one or more biocompatible polymers or copolymers, as Applicant believes that claim 14 as amended is novel

and nonobvious over the cited art. Claims 25 and 27 were amended to recite the claim limitations from claims 1 and 23. Claims 26 and 28 were amended to recite the claim limitations from claims 6 and 24.

The amendments presented herein add no new matter. Applicant respectfully requests entry and consideration of the foregoing amendments, which are intended to place this case in condition for allowance.

## II. Claims 1-12, 15-24 and 29-37 Are Patentable Over Dunn et al.

Claims 1-12, 15-24 and 29-37 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dunn et al., U.S. Patent No. 4,655,777. The Examiner is of the opinion that although Dunn et al. does not disclose the specific porosity, the reference does disclose the use of ceramic fibers that are highly porous, and that porosity is an optimizable feature. The Examiner asserts that it would be obvious to one of ordinary skill in the art to have the porosity of the material be in the range of 50 to 95 volume percent. The Examiner also asserts that it would be obvious that the glass fibers have a high porosity since ceramic fibers, which have a high porosity, can be used as well. Applicant respectfully traverses the Examiner's rejections based on the amended claims presented herein.

As amended, Applicant's claims are directed to sintered scaffold materials and sintered glass scaffolds wherein glass or ceramic fibers are *sintered together* to form the sintered scaffold. The result of sintering fibers together is that an openly porous scaffold is formed. Applicant submits herewith micrographs depicting such sintered scaffolds (Appendix A). The openly porous three-dimensional structure of the claimed scaffolds provides many advantages over implant materials known in the art. When used as implants, Applicant's claimed scaffolds provide physical characteristics that impart excellent compatibility with the living body,

promoting early formation of new bone and integrating with growing hard tissue of the living body (page 5, lines 12-15). The claimed scaffolds allow living tissue ingrowth and serve as a base that guides tissue growth (page 7, lines 14-16). Additionally, Applicant has discovered that the claimed scaffolds increase wound stability, which is a critical factor influencing healing of a wound (page 6, lines 7-16).

In contrast to the claimed invention, Dunn et al. fails to teach or suggest glass or ceramic fibers sintered together to form a scaffold. Instead, Dunn et al. teaches *polymer matrices* into which fibers can be incorporated (column 11, lines 2). Dunn et al. only teaches the use of ceramic fibers in the context of these polymer matrices: “[f]or the high-strength, high-modulus, bioabsorbable ceramic or glass fibers to be useful, they *must* be *incorporated into a biodegradable polymer matrix*” (column 9, lines 41-43, emphasis added). Although Dunn et al. does teach sintering ceramic materials, this is merely to prepare calcium phosphate ceramic cakes and reinforcing fibers of “high purity and single-phase nature” (column 3, line 41 to column 4, line 42), and not for forming a sintered scaffold of glass or ceramic fibers sintered together, as claimed by Applicant.

Furthermore, the matrices of Dunn et al. are suitable as fracture-fixation plates or devices (column 3, lines 16-22), not scaffolds which support living tissue ingrowth. Dunn et al. teaches that their fixation plates are designed to be resorbed by the body, thus gradually transferring the load to the healing bone (column 10, lines 25-30). Dunn et al. is thus concerned with the structural rigidity needed for the polymer plate or device to maintain support while the bone heals (column 9, lines 44-46). Dunn et al. is not concerned with physical characteristics that would promote formation of new bone within their matrices, such as open porosity. Although the ceramic fibers of Dunn et al. may be porous, Dunn et al. teaches that “the polymer *completely encases the fibers*” (column 10, lines 30-34, emphasis added). Thus none or very

little of the porosity imparted by the fibers would be available at the surface of the matrices to promote bone tissue ingrowth. Furthermore, Dunn et al. fails to teach or suggest that their polymer matrices are porous and, accordingly, suitable for bone ingrowth.

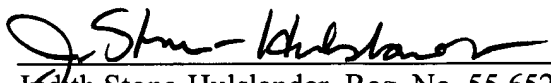
Thus, Dunn et al. fails to teach each and every element of the claimed invention and, accordingly, Dunn et al. fails to render the claimed invention obvious. Therefore, Applicant respectfully requests that the Examiner withdraw the rejection of claims 1-12, 15-24 and 29-37 under 35 U.S.C. §103(a).

### III. CONCLUSION

Having addressed all outstanding issues, Applicant respectfully requests entry and consideration of the foregoing amendments and reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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